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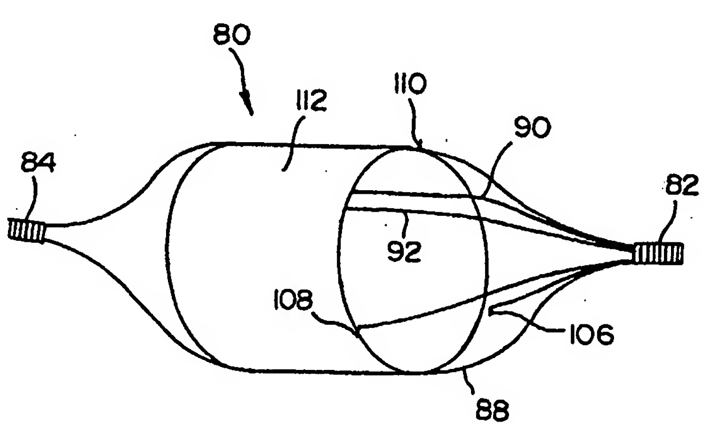
(54) Title: REMOVABLE LUNG REDUCTION DEVICES, SYSTEMS, AND METHODS



(57) Abstract: An air passageway obstruction device includes a frame structure and a flexible membrane overlying the frame structure. The frame structure is collapsible upon advancement of the device into the air passageway, expandable into a rigid structure upon deploying in the air passageway and recollapsible upon removal from the air passageway. The flexible membrane obstructs inhaled air flow into a lung portion communicating with the air passageway. The device may be removed after deployment in an air passageway by recollapsing the device and pulling the device proximally through a catheter.

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REMOVABLE LUNG REDUCTION DEVICES, SYSTEMS, AND METHODS

BACKGROUND OF THE INVENTION

[1] The present invention is generally directed to a treatment of Chronic Obstructive Pulmonary Disease (COPD). The present invention is more particularly directed to removable air passageway obstruction devices, and systems and methods for removing the devices.

[2] Chronic Obstructive Pulmonary Disease (COPD) has become a major cause of morbidity and mortality in the United States over the last three decades. COPD is characterized by the presence of airflow obstruction due to chronic bronchitis or emphysema. The airflow obstruction in COPD is due largely to structural abnormalities in the smaller airways. Important causes are inflammation, fibrosis, goblet cell metaplasia , and smooth muscle hypertrophy in terminal bronchioles.

[3] The incidence, prevalence, and health-related costs of COPD are on the rise. Mortality due to COPD is also on the rise. In 1991 COPD was the fourth leading cause of death in the United States and had increased 33% since 1979.

[4] COPD affects the patient's whole life. It has three main symptoms: cough; breathlessness; and wheeze. At first, breathlessness may be noticed when running for a bus, digging in the garden, or walking up hill. Later, it may be noticed when simply walking in the kitchen. Over time, it may occur with less and less effort until it is present all of the time.

[5] COPD is a progressive disease and currently has no cure. Current treatments for COPD include the prevention of further respiratory damage, pharmacotherapy, and surgery. Each is discussed below.

[6] The prevention of further respiratory damage entails the adoption of a healthy lifestyle. Smoking cessation is believed to be the single most important therapeutic intervention. However, regular exercise and weight control are also important. Patients whose symptoms restrict their daily activities or who otherwise have an impaired quality of life may require a pulmonary rehabilitation program

including ventilatory muscle training and breathing retraining. Long-term oxygen therapy may also become necessary.

[7] Pharmacotherapy may include bronchodilator therapy to open up the airways as much as possible or inhaled ß-agonists. For those patients who respond poorly to the foregoing or who have persistent symptoms, Ipratropium bromide may be indicated. Further, courses of steroids, such as corticosteroids, may be required. Lastly, antibiotics may be required to prevent infections and influenza and pheumococcal vaccines may be routinely administered. Unfortunately, there is no evidence that early, regular use of pharmacotherapy will alter the progression of COPD.

[8] About 40 years ago, it was first postulated that the tethering force that tends to keep the intrathoracic airways open was lost in emphysema and that by surgically removing the most affected parts of the lungs, the force could be partially restored. Although the surgery was deemed promising, the procedure was abandoned.

[9] The lung volume reduction surgery (LVRS) was later revived. In the early 1990's, hundreds of patients underwent the procedure. However, the procedure has fallen out of favor due to the fact that Medicare stopping reimbursing for LVRS. Unfortunately, data is relatively scarce and many factors conspire to make what data exists difficult to interpret. The procedure is currently under review in a controlled clinical trial. What data does exist tends to indicate that patients benefited from the procedure in terms of an increase in forced expiratory volume, a decrease in total lung capacity, and a significant improvement in lung function, dyspnea, and quality of life. However, the surgery is not without potential complications. Lung tissue is very thin and fragile. Hence, it is difficult to suture after sectioning. This gives rise to potential infection and air leaks. In fact, nearly thirty percent (30%) of such surgeries result in air leaks.

[10] Improvements in pulmonary function after LVRS have been attributed to at least four possible mechanisms. These include enhanced elastic recoil, correction of ventilation/perfusion mismatch, improved efficiency of respiratory muscaulature, and improved right ventricular filling.

[11] Lastly, lung transplantation is also an option. Today, COPD is the most common diagnosis for which lung transplantation is considered. Unfortunately, this consideration is given for only those with advanced COPD. Given the limited availability of donor organs, lung transplant is far from being available to all patients.

[12] In view of the need in the art for new and improved therapies for COPD which provide more permanent results than pharmacotherapy while being less invasive and traumatic than LVRS, at least two new therapies have recently been proposed.

[13] Both of these new therapies provide lung size reduction by permanently collapsing at least a portion of a lung.

[14] In accordance with a first one of these therapies, and as described in U.S. Patent No. 6,258,100 assigned to the assignee of the present invention and incorporated herein by reference, a lung may be collapsed by obstructing an air passageway communicating with the lung portion to be collapsed. The air passageway may be obstructed by placing an obstructing member in the air passageway. The obstructing member may be a plug-like device which precludes air flow in both directions or a one-way valve which permits air to be exhaled from the lung portion to be collapsed while precluding air from being inhaled into the lung portion. Once the air passageway is sealed, the residual air within the lung will be absorbed over time to cause the lung portion to collapse.

[15] As further described in U.S. Patent No. 6,258,100, the lung portion may be collapsed by inserting a conduit into the air passageway communicating with the lung portion to be collapsed. An obstruction device, such as a one-way valve is then advanced down the conduit into the air passageway. The obstruction device is then deployed in the air passageway for sealing the air passageway and causing the lung portion to be collapsed.

[16] The second therapy is fully described in copending U.S. Application Serial No. 09/534,244, filed March 23, 2000, for LUNG CONSTRICTION APPARATUS AND METHOD and, is also assigned to the assignee of the present invention. As described therein, a lung constriction device including a sleeve of elastic material is configured to cover at least a portion of a lung. The sleeve has a pair of opened ends to permit the lung portion to be drawn into the sleeve. Once

drawn therein, the lung portion is constricted by the sleeve to reduce the size of the lung portion.

[17] Both therapies hold great promise for treating COPD. Neither therapy requires sectioning and suturing of lung tissue.

[18] While either therapy alone would be effective in providing lung size reduction and treatment of COPD, it has recently been proposed that the therapies may be combined for more effective treatment. More specifically, it has been proposed that the therapies could be administered in series, with the first mentioned therapy first applied acutely for evaluation of the effectiveness of lung size reduction in a patient and which lung portions should be reduced in size to obtain the best results. The first therapy is ideal for this as it is noninvasive and could be administered in a physician's office. Once the effectiveness of lung size reduction is confirmed and the identity of the lung portions to be collapsed is determined, the more invasive second mentioned therapy may be administered.

[19] In order to combine these therapies, or simply administer the first therapy for evaluation, it will be necessary for at least some of the deployed air passageway obstruction devices to be removable. Unfortunately, such devices as currently known in the art are not suited for removal. While such devices are expandable for permanent deployment, such devices are not configured or adapted for recollapse after having once been deployed in an air passageway to facilitate removal. Hence, there is a need in the art for air passageway obstruction devices which are removable after having been deployed and systems and methods for removing them.

SUMMARY OF THE INVENTION

[20] The invention provides device for reducing the size of a lung comprising an obstructing structure dimensioned for insertion into an air passageway communicating with a portion of the lung to be reduced in size, the obstructing structure having an outer dimension which is so dimensioned when deployed in the air passageway to preclude air from flowing into the lung portion to collapse the

portion of the lung for reducing the size of the lung, the obstructing structure being collapsible to permit removal of the obstruction device from the air passageway.

[21] The invention further provides an assembly comprising a device for reducing the size of a lung, the device being dimensioned for insertion into an air passageway communicating with a portion of the lung to be reduced in size, the device having an outer dimension which is so dimensioned when deployed in the air passageway to preclude air from flowing into the lung portion to collapse the portion of the lung for reducing the size of the lung, a catheter having an internal lumen and being configured to be passed down a trachea, into the air passageway, and a retractor dimensioned to be passed down the internal lumen of the catheter, seizing the device, and pulling ~~the~~ obstruction device proximally into the internal lumen to remove the device from the air passageway. The device is collapsible after having been deployed to permit the device to be pulled proximally into the internal lumen of the catheter by the retractor.

[22] The invention further provides a method of removing a deployed air passageway obstruction device from an air passageway in which the device is deployed. The method includes the steps of passing a catheter, having an internal lumen, down a trachea and into the air passageway, advancing a retractor down the internal lumen of the catheter to the device, seizing the device with the retractor, collapsing the device to free the device from deployment in the air passageway, and pulling the device with the retractor proximally into the internal lumen of the catheter.

[23] The invention still further provides an air passageway obstruction device comprising a frame structure, and a flexible membrane overlying the frame structure. The frame structure is collapsible upon advancement of the device into the air passageway, expandable into a rigid structure upon deployment in the air passageway whereby the flexible membrane obstructs inhaled air flow into a lung portion communicating with the air passageway, and re-collapsible upon removal from the air passageway.

[24] The invention still further provides an air passageway obstruction device comprising frame means for forming a support structure, and flexible membrane means overlying the support structure. The frame means is expandable

to an expanded state within an air passageway to position the membrane means for obstructing air flow within the air passageway and is collapsible for removal of the device from the air passageway.

BRIEF DESCRIPTION OF THE DRAWINGS

[25] The features of the present invention which are believed to be novel are set forth with particularity in the appended claims. The invention, together with further objects and advantages thereof, may best be understood by making reference to the following description taken in conjunction with the accompanying drawings, in the several figures of which like referenced numerals identify identical elements, and wherein:

[26] FIG. 1 is a simplified sectional view of a thorax illustrating a healthy respiratory system;

[27] FIG. 2 is a sectional view similar to FIG. 1 but illustrating a respiratory system suffering from COPD and the execution of a first step in treating the COPD condition in accordance with the present invention;

[28] FIG. 3 is a perspective view, illustrating the frame structure of a removable air passageway obstruction device embodying the present invention;

[29] FIG. 4 is a perspective view of the complete air passageway obstruction device of FIG. 3;

[30] FIG. 5 is an end view of the device of FIG. 3 illustrating its operation for obstructing inhaled air flow;

[31] FIG. 6 is another end view of the device of FIG. 3 illustrating its operation for permitting exhaled air flow;

[32] FIG. 7 is a perspective view of the device of FIG. 3, illustrating its operation for permitting partial exhaled air flow;

[33] FIG. 8 is a side view illustrating a first step in removing the device of FIG. 3 in accordance with one embodiment of the present invention;

[34] FIG. 9 is another side view illustrating the collapse of the device of FIG. 3 as it is removed from an air passageway;

[35] FIG. 10 is a side view illustrating an initial step in the removal of the device of FIG. 3 in accordance with another embodiment of the present invention;

[36] FIG. 11 is a side view illustrating engagement of the frame structure of the device with a catheter during removal of the device;

[37] FIG. 12 is a side view illustrating the collapse of the device by the catheter during removal of the device;

[38] FIG. 13 is a side view of another air passageway obstruction device embodying the present invention during an initial step in its removal from an air passageway;

[39] FIG. 14 is another side view of the device of FIG. 13 illustrating its collapse during removal from the air passageway;

[40] FIG. 15 is a perspective view of the frame structure of another removable air passageway obstruction device embodying the present invention;

[41] FIG. 16 is a cross-sectional side view of the device of FIG. 15 shown in a deployed state;

[42] FIG. 17 is a perspective side view of the device of FIG. 15 shown in a deployed state;

[43] FIG. 18 is a side view illustrating an initial step in removing the device of FIG. 15 from an air passageway;

[44] FIG. 19 is a side view illustrating an intermediate step in the removal of the device of FIG. 15; and

[45] FIG. 20 is a side view illustrating the collapse of the device of FIG. 15 during its removal from an air passageway.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[46] Referring now to FIG. 1, it is a sectional view of a healthy respiratory system. The respiratory system 20 resides within the thorax 22 which occupies a space defined by the chest wall 24 and the diaphragm 26.

[47] The respiratory system 20 includes the trachea 28, the left mainstem bronchus 30, the right mainstem bronchus 32, the bronchial branches 34, 36, 38, 40, and 42 and sub-branches 44, 46, 48, and 50. The respiratory system 20 further

includes left lung lobes 52 and 54 and right lung lobes 56, 58, and 60. Each bronchial branch and sub-branch communicates with a respective different portion of a lung lobe, either the entire lung lobe or a portion thereof. As used herein, the term "air passageway" is meant to denote either a bronchial branch or sub-branch which communicates with a corresponding individual lung lobe or lung lobe portion to provide inhaled air thereto or conduct exhaled air therefrom.

[48] Characteristic of a healthy respiratory system is the arched or inwardly arcuate diaphragm 26. As the individual inhales, the diaphragm 26 straightens to increase the volume of the thorax 22. This causes a negative pressure within the thorax. The negative pressure within the thorax in turn causes the lung lobes to fill with air. When the individual exhales, the diaphragm returns to its original arched condition to decrease the volume of the thorax. The decreased volume of the thorax causes a positive pressure within the thorax which in turn causes exhalation of the lung lobes.

[49] In contrast to the healthy respiratory system of FIG. 1, FIG. 2 illustrates a respiratory system suffering from COPD. Here it may be seen that the lung lobes 52, 54, 56, 58, and 60 are enlarged and that the diaphragm 26 is not arched but substantially straight. Hence, this individual is incapable of breathing normally by moving the diaphragm 28. Instead, in order to create the negative pressure in the thorax 22 required for breathing, this individual must move the chest wall outwardly to increase the volume of the thorax. This results in inefficient breathing causing these individuals to breathe rapidly with shallow breaths. It has been found that the apex portion 62 and 66 of the upper lung lobes 52 and 56, respectively, are most affected by COPD.

[50] In accordance with this embodiment of the present invention, COPD treatment or evaluation is initiated by feeding a conduit or catheter 70 down the trachea 28, into a mainstream bronchus such as the right mainstem bronchus 32, and into an air passageway such as the bronchial branch 42 or the bronchial sub-branch 50. An air passageway obstruction device embodying the present invention is then advanced down an internal lumen 71 of the catheter 70 for deployment in the air passageway. Once deployed, the obstruction device precludes inhaled air from

entering the lung portion to be collapsed. In accordance with the present invention, it is preferable that the obstruction device take the form of a one-way valve. In addition to precluding inhaled air from entering the lung portion, the device further allows air within the lung portion to be exhaled. This results in more rapid collapse of the lung portion. However, obstruction devices which preclude both inhaled and exhaled air flow are contemplated as falling within the scope of the invention.

[51] The catheter 70 is preferably formed of flexible material such as polyethylene. Also, the catheter 70 is preferably preformed with a bend 72 to assist the feeding of the catheter from the right mainstem bronchus 32 into the bronchial branch 42.

[52] FIGS. 3 and 4 show an air passageway obstruction device 80 embodying the present invention. The device 80 includes a proximal end 82 and a distal end 84. The device 80 further includes a frame structure 86 including frame supports 88, 90, and 92.

[53] Each of the frame supports has a shape to define a generally cylindrical center portion 94 and a pair of oppositely extending inwardly arcuate conical end portions 96 and 98. The frame structure further includes a plurality of fixation members 100, 102, and 104 which extend distally from the proximal end 82. The fixation members have the generally conical shape and terminate in fixation projections or anchors 106, 108, and 110 which extend radially outwardly.

[54] Overlying and partially enclosing the frame structure 86 is a flexible membrane 112. The flexible membrane extends over the generally cylindrical and conical portions 94 and 98 defined by the frame structure. Hence, the flexible membrane is opened in the proximal direction.

[55] The flexible membrane may be formed of silicone or polyurethane, for example. It may be secured to the frame structure in a manner known in the art such as by crimping, riveting, or adhesion.

[56] The frame structure 86 and the device 80 are illustrated in FIGS. 3 and 4 as the device would appear when fully deployed in an air passageway. The frame structure supports and frame structure fixation members are preferably formed of stainless steel or Nitinol or other suitable material which has memory of an original

shape. The frame structure permits the device to be collapsed for advancement down the internal lumen 71 of the catheter 70 into the air passageway where the device is to be deployed. Once the point of deployment is reached, the device is expelled from the catheter to assume its original shape in the air passageway. In doing so, the generally cylindrical portion 94 contacts the inner wall of the air passageway and the fixation projections 106, 108, and 110 pierce the wall of the air passageway for fixing or anchoring the device 80 within the air passageway.

[57] When the device 80 is deployed, the frame structure 86 and flexible membrane 112 form an obstructing structure or one-way valve. FIGS. 5 and 6 show the valve action of the device 80 when deployed in an air passageway, such as the bronchial branch 42.

[58] As shown in FIG. 5, during inhalation, the flexible membrane is filled with air and expands outwardly to obstruct the air passageway 42. This precludes air from entering the lung portion being collapsed. However, as shown in FIG. 6, during expiration, the flexible membrane 112 deflects inwardly to only partially obstruct the air passageway 42. This enables air, which may be in the lung portion being collapsed, to be exhaled for more rapid collapse of the lung portion. FIG. 7 is another view showing the device 80 during expiration with a portion 114 of the membrane 112 deflected inwardly.

[59] FIGS. 8 and 9 illustrate a manner in which the device 80 may be removed from the air passageway 42 in accordance with one embodiment of the present invention. As previously mentioned, it may be desired to remove the device 80 if it is only used for evaluating the effectiveness of collapsing a lung portion or if it is found the more effective treatment may be had with the collapse of other lung portions.

[60] The device 80 is shown in FIG. 8 in a fully deployed state. The catheter 70 having the internal lumen 71 is advanced to the proximal end of the device 80. In FIG. 8 it may be noted that the fixation members 102 and 104 define a larger conical radius than the frame supports 88 and 90. Hence, when the proximal end of the device is engaged by a retractor and the catheter 70 is moved distally as shown in FIG. 9, the internal lumen of the catheter engages the fixation members

102 and 104 before it engages the frame supports 88 and 90. This causes the fixation projections to first disengage the inner wall of the air passageway 42. With the device now free of the air passageway side wall, the retractor may be used to pull the device into the internal lumen 71 of the catheter 70 causing the support structure and thus the device to collapse. The collapsed device may now fully enter the internal lumen of the catheter for removal.

[61] FIGS. 10-12 show another embodiment of the present invention for removing the device 80 from the air passageway 42. Here, the catheter 70 is fed down a bronchoscope 118 to the device 80. The retractor takes the form of a forceps 120.

[62] In FIG. 10 it may be seen that the forceps has just engaged the proximal end 82 of the device 80. In FIG. 11 the forceps 120 is held stationary while the catheter 70 is advanced distally so that the internal lumen 71 of the catheter 70 engages the fixation members 102 and 104. Further advancement of the catheter 70 as seen in FIG. 12 deflects the fixation projections 110 and 108 inwardly away from the inner wall of the air passageway 42. Now, the forceps may be used to pull the device 80 into the internal lumen 71 of the catheter 70 for removal of the device 80 from the air passageway 42.

[63] FIGS. 13 and 14 show another removable air passageway obstruction device 130 and a method of removing it from an air passageway in accordance with the present invention. The device 130 is shown in FIG. 13 deployed in the air passageway 42 and the catheter 70 is in ready position to remove the device 130 from the air passageway 42.

[64] The device 130 is of similar configuration to the device 80 previously described. Here however, the fixation members 136 and 138 are extensions of the frame supports 132 and 134, respectively. To that end, it will be noted in FIG. 13 that the frame supports 132 and 134 cross at a pivot point 140 at the distal end 142 of the device 130. They extend distally and then are turned back at an acute angle to terminate at fixation or anchor ends 146 and 148. When the device is deployed as shown in FIG. 13, the cylindrical portions of the support frame engage the inner wall of the air passageway 42 and the fixation points 146 and 148 project into the inner

wall of the air passageway 42 to maintain the device in a fixed position. The flexible membrane 150 extends from the dashed line 152 to the pivot or crossing point 140 of the frame supports 132 and 134 to form a one-way valve.

[65] When the device is to be removed, the frame structure of the device 130 is held stationary by a retractor within the catheter 70 and the catheter is advanced distally. When the catheter 70 engages the frame supports 132 and 134, the frame supports are deflected inwardly from their dashed line positions to their solid line positions. This also causes the fixation members 136 and 138 to be deflected inwardly from their dashed line positions to their solid line positions in the direction of arrows 154. These actions disengage the device 130 from the inner wall of the air passageway 42. Now, the retractor may pull the device into the internal lumen 71 of the catheter 70 for removal of the device 130 from the air passageway 42.

[66] FIGS. 15-17 show a still further removable air passageway obstruction device 160 embodying the present invention. As shown in the initial collapsed state in FIG. 15, the device 160 includes a plurality of frame supports 162, 164, 166, and 168. The frame supports extend between a proximal ring 170 and a distal ring 172. The device 160 is preferably laser cut from a sheet of Nitinol.

[67] Since each of the frame supports are identical, only frame support 164 will be described herein. As will be noted, the support 164 includes a bend point 174 with a relatively long section 176 extending distally from the bend point 174 and a relatively short section 178 extending proximally from the bend point 174. The short section 178 includes a fixation projection or anchor 180 extending slightly distally from the bend point 174.

[68] FIGS. 16 and 17 show the device 160 in its deployed configuration. When the device is deployed, it is advanced down a catheter to its deployment site in its collapsed state as shown in FIG. 15. When the deployment site is reached, the device 160 is held outside of the catheter and the rings 170 and 172 are pulled toward each other. This causes the device to bend at the bend points of the frame supports. This forms fixation projections 180, 182, and 184 extending into the inner wall of the air passageway to fix the device in position.

[69] The relatively long sections of the frame supports are covered with a flexible membrane 186 as shown in FIGS. 16 and 17 to form a one-way valve. The valve functions as previously described to obstruct inhaled air flow but to permit exhaled air flow.

[70] FIGS. 18-20 illustrate a manner of removing the device 160 from an air passageway. Once again a catheter 70 is advanced down a bronchoscope 118 to the device 160. Next, a retractor including a forceps 120 and pin 190 are advanced to the device. The pin 190, carrying a larger diameter disk 192, extends into the device as the forceps 120 grasps the proximal ring 170 of the device 160. The pin 190 continues to advance until the disk 192 engages the distal ring 172 of the device 160 as shown in FIG. 19. Then, while the forceps 120 holds the proximal ring 170, the pin 190 and disk 192 are advanced distally carrying the distal ring 172 distally. This causes the device 160 to straighten and collapse as shown in FIG. 20. Now, the forceps 120, pin 190, and the device 160 may be pulled into the internal lumen 71 of the catheter 70 for removal of the device. As will be appreciated by those skilled in the art, the foregoing steps may be reversed for deploying the device 160.

[71] While particular embodiments of the present invention have been shown and described, modifications may be made, and it is therefore intended in the appended claims to cover all such changes and modifications which fall within the true spirit and scope of the invention.

What is claimed is:

1. A device for reducing the size of a lung comprising an obstructing structure dimensioned for insertion into an air passageway communicating with a portion of the lung to be reduced in size, the obstructing structure having an outer dimension which is so dimensioned when deployed in the air passageway to preclude air from flowing into the lung portion to collapse the portion of the lung for reducing the size of the lung, the obstructing structure being collapsible to permit removal of the obstruction device from the air passageway.

2. The device of claim 1 wherein the obstructing structure forms a one-way valve.

3. The device of claim 1 further including at least one anchor that anchors the device within the air passageway when the device is deployed and wherein the at least one anchor is releasable during collapse of the obstructing structure and removal of the device from the air passageway.

4. The device of claim 1 wherein the obstructing structure includes a collapsible frame and a flexible membrane overlying the collapsible frame.

5. The device of claim 4 wherein the flexible membrane has an opened proximal end and a closed distal end.

6. The device of claim 5 wherein the flexible membrane inflates to inhaled air to preclude air from flowing into the lung portion and at least partially deflates to exhaled air to permit air to flow from the lung portion.

7. The device of claim 4 wherein the collapsible frame includes at least one anchor that anchors the device within the air passageway when deployed and wherein the at least one anchor is releasable during collapse of the collapsible frame and removal of the device from the air passageway.

8. An assembly comprising:

a device for reducing the size of a lung, the device being dimensioned for insertion into an air passageway communicating with a portion of the lung to be reduced in size, the device having an outer dimension which is so dimensioned when deployed in the air passageway to preclude air from

flowing into the lung portion to collapse the portion of the lung for reducing the size of the lung;

a catheter having an internal lumen and being configured to be passed down a trachea, into the air passageway; and

a retractor dimensioned to be passed down the internal lumen of the catheter, seizing the device, and pulling the obstruction device proximally into the internal lumen to remove the device from the air passageway,

the device being collapsible after having been deployed to permit the device to be pulled proximally into the internal lumen of the catheter by the retractor.

9. The assembly of claim 8 wherein the device is collapsible by the catheter as the device is pulled into the internal lumen of the catheter by the retractor.

10. The assembly of claim 8 wherein the retractor includes collapsing means for collapsing the device before pulling the device into the internal lumen of the catheter.

11. The assembly of claim 8 wherein the device is a one-way valve.

12. The assembly of claim 8 wherein the device further includes at least one anchor that anchors the device within the air passageway when the device is deployed and wherein the at least one anchor is releasable as the device is pulled proximally into the internal lumen of the catheter and collapsed for removal from the air passageway.

13. The assembly of claim 8 wherein the device includes a collapsible frame and a flexible membrane overlying the collapsible frame.

14. The assembly of claim 13 wherein the flexible membrane has an opened proximal end and a closed distal end.

15. The assembly of claim 14 wherein the flexible membrane inflates to inhaled air to preclude air from flowing into the lung portion and at least partially deflates to exhaled air to permit air to flow from the lung portion.

16. The assembly of claim 13 wherein the collapsible frame includes at least one anchor that anchors the device within the air passageway when deployed

and wherein the at least one anchor is releasable during collapse of the collapsible frame and removal of the device from the air passageway.

17. A method of removing a deployed air passageway obstruction device from an air passageway in which the device is deployed, the method including the steps of:

passing a catheter, having an internal lumen, down a trachea and into the air passageway;

advancing a retractor down the internal lumen of the catheter to the device;

seizing the device with the retractor;

collapsing the device to free the device from deployment in the air passageway; and

pulling the device with the retractor proximally into the internal lumen of the catheter.

18. The method of claim 17 wherein the collapsing step is performed as the device is pulled into the internal lumen of the catheter.

19. The method of claim 18 wherein the device is collapsed by the catheter.

20. The method of claim 19 wherein the device is collapsed by the internal lumen of the catheter.

21. The method of claim 17 wherein the device is collapsed prior to being pulled into the internal lumen of the catheter.

22. The method of claim 21 wherein the device is collapsed by the retractor.

23. The method of claim 17 wherein the device includes at least one anchor for fixing the device in the air passageway when deployed and wherein the collapsing step includes the step of releasing the at least one anchor from the air passageway.

24. An air passageway obstruction device comprising:

a frame structure; and

a flexible membrane overlying the frame structure,

the frame structure being collapsible upon advancement of the device into the air passageway, expandable into a rigid structure upon deployment in the air passageway whereby the flexible membrane obstructs inhaled air flow into a lung portion communicating with the air passageway, and recollapsible upon removal from the air passageway.

25. The device of claim 24 wherein the frame structure and flexible membrane form a one-way valve.

26. The device of claim 25 wherein the flexible membrane inflates to inhaled air to obstruct the air passageway and at least partially deflates to exhaled air to at least partially unobstruct the air passageway.

27. The device of claim 24 wherein the frame structure includes at least one anchor that engages and fixes the device in the air passageway upon deployment.

28. The device of claim 27 wherein the at least one anchor is releasable from engagement with the air passageway upon recollapse of the frame structure.

29. An air passageway obstruction device comprising:

frame means for forming a support structure; and

flexible membrane means overlying the support structure,

the frame means being expandable to an expanded state within an air passageway to position the membrane means for obstructing air flow within the air passageway and being collapsible for removal of the device from the air passageway.

30. The device of claim 29 wherein the frame means and flexible membrane means form a one-way valve when the frame means is in the expanded state.

31. The device of claim 29 wherein the frame means further includes anchor means for fixing the device in the air passageway when the frame means is in the expanded state.

32. The device of claim 31 wherein the anchor means releases the device from the air passageway when the frame means collapses for removal of the device from the air passageway.

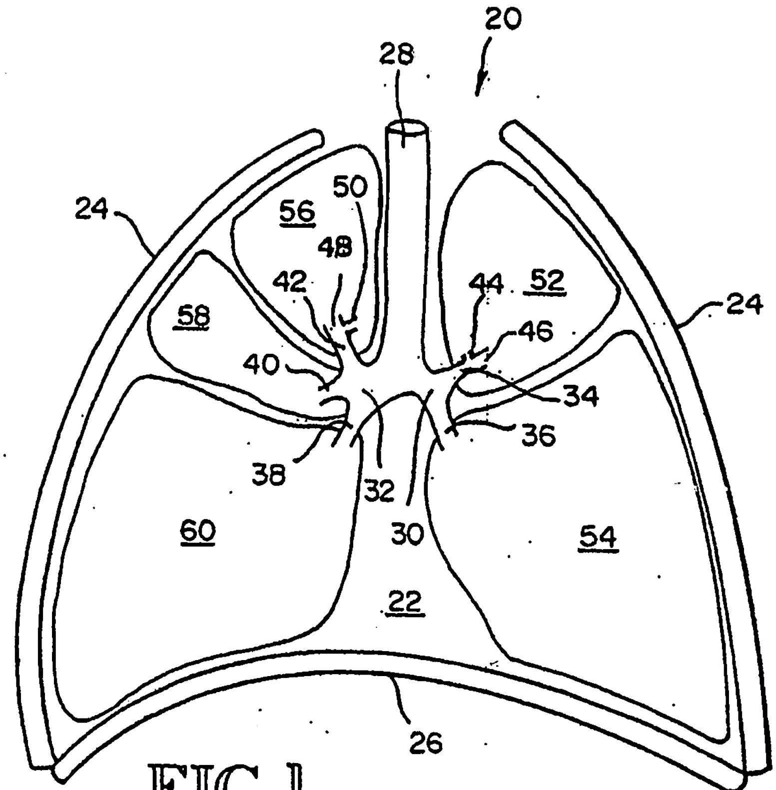
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FIG. 1

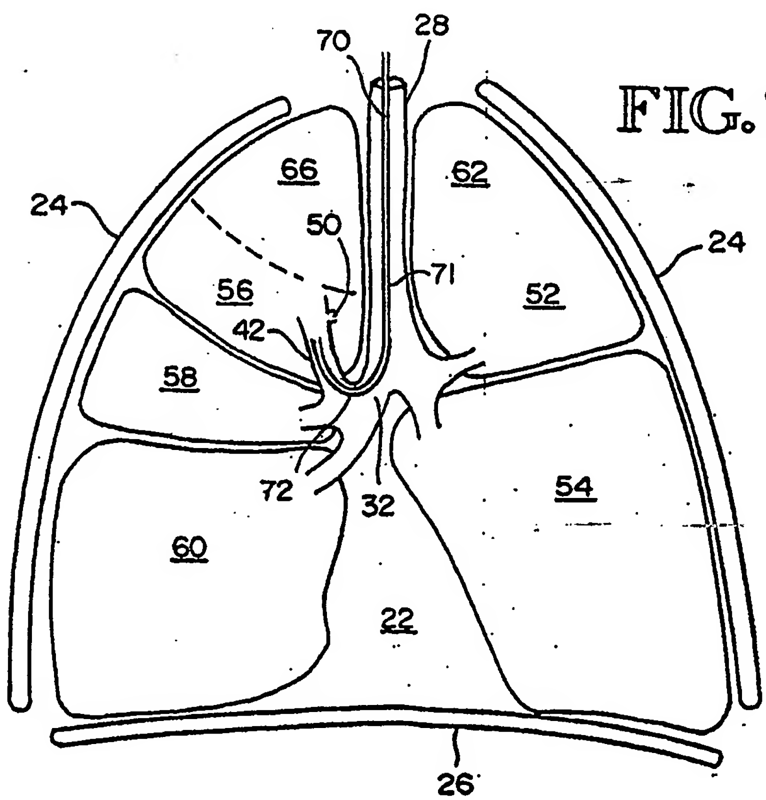
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FIG. 2

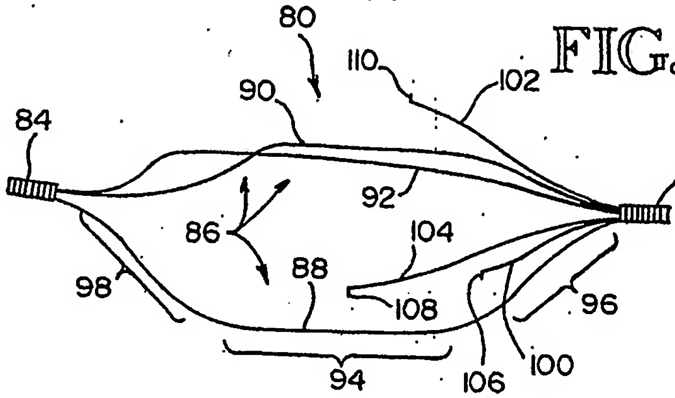


FIG.3

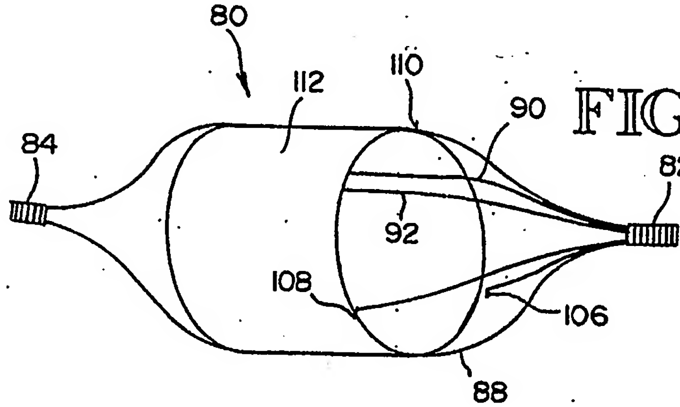
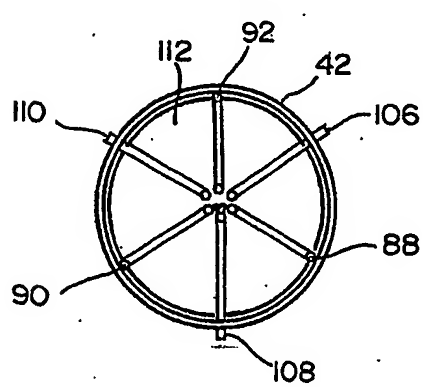


FIG.4

FIG.5



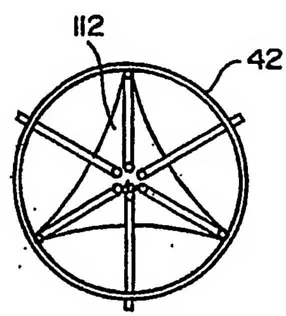


FIG.6

FIG. 7

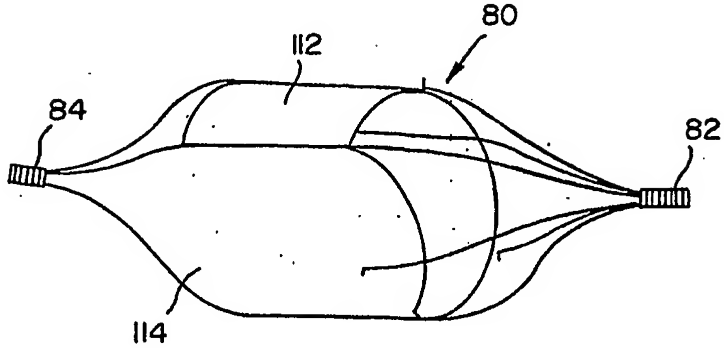


FIG. 8

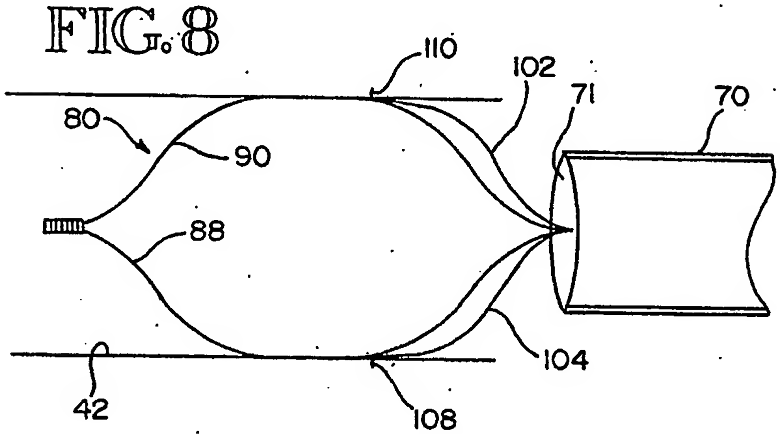


FIG. 9

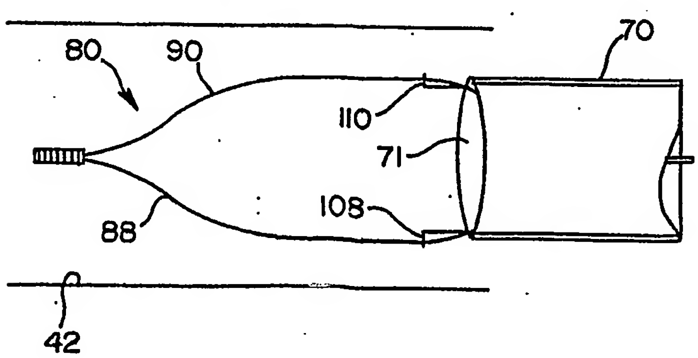


FIG.10

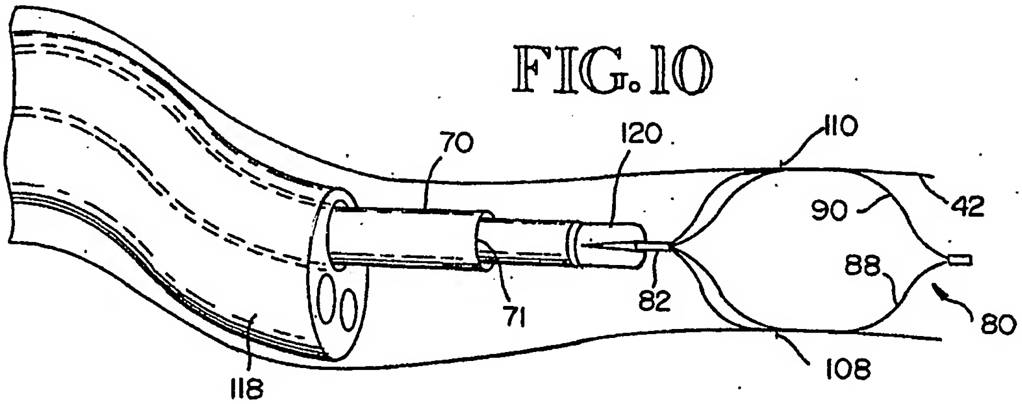
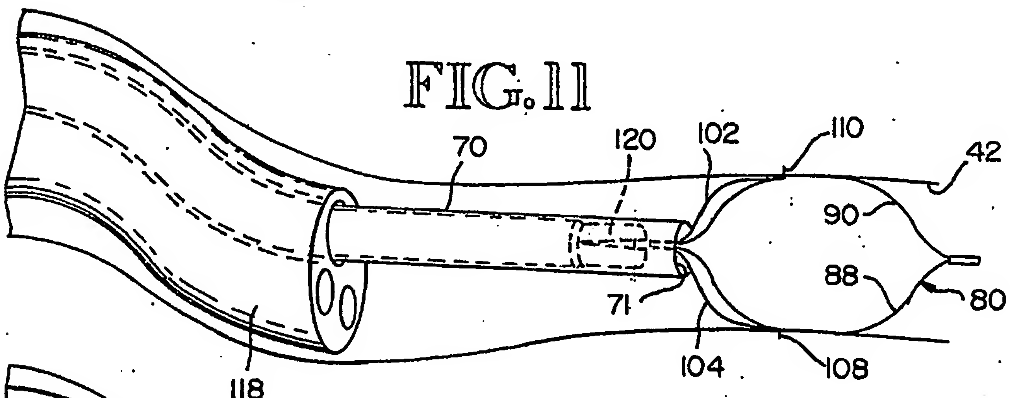


FIG.11



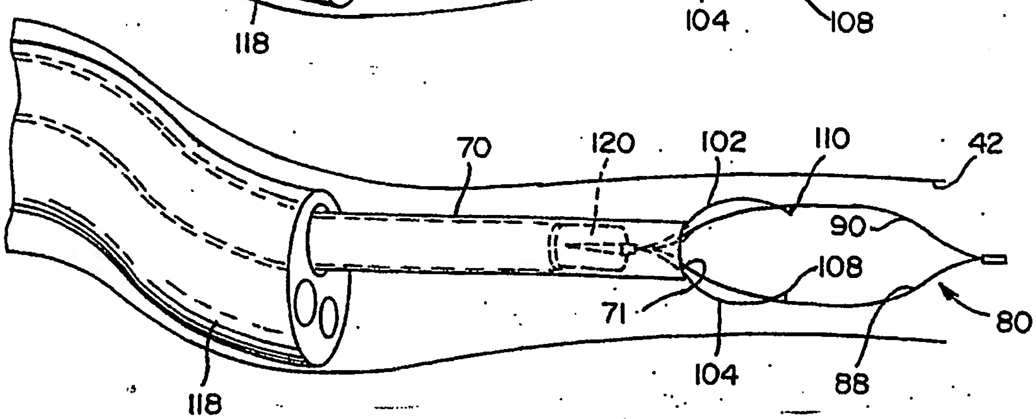
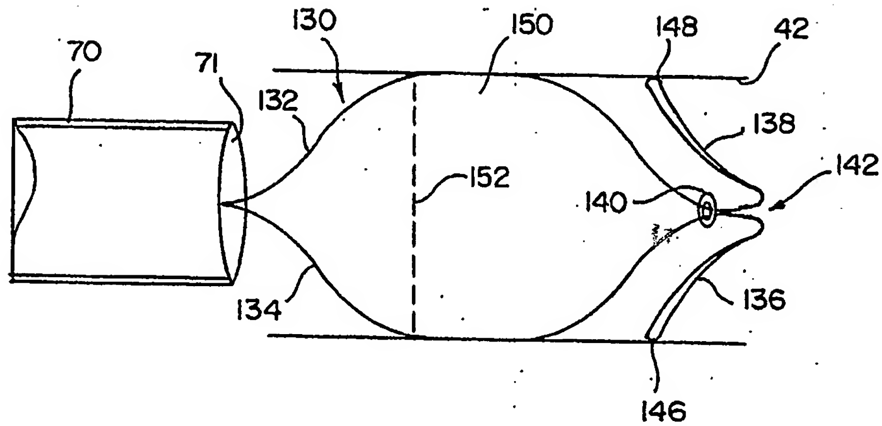


FIG.12

FIG. 13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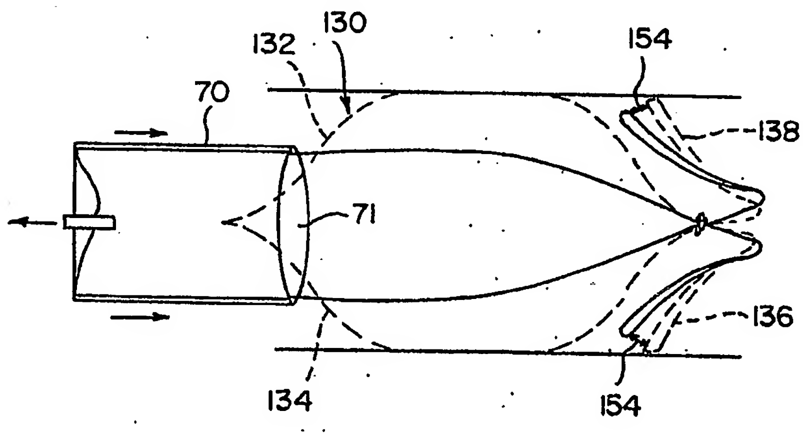
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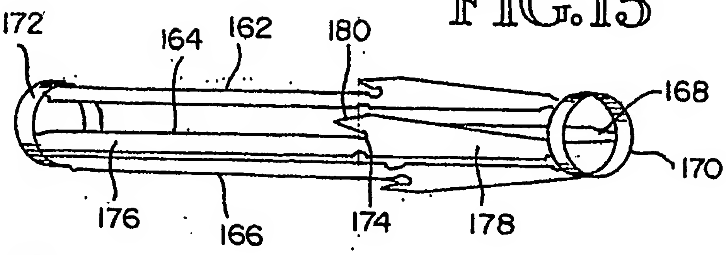
FIG. 14

FIG. 15



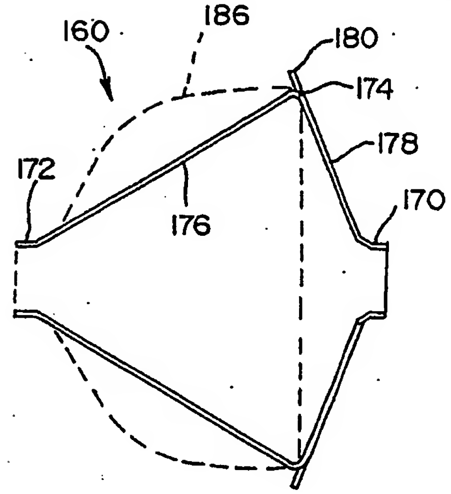


FIG. 16

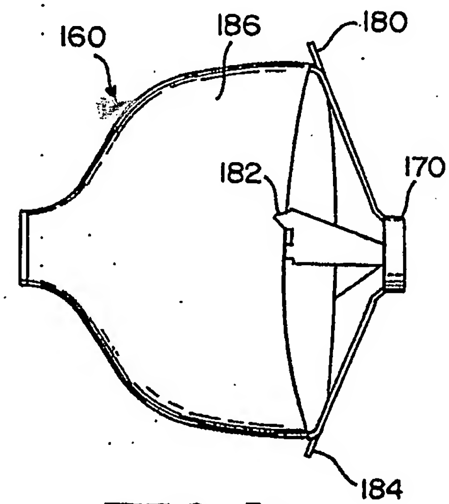


FIG. 17

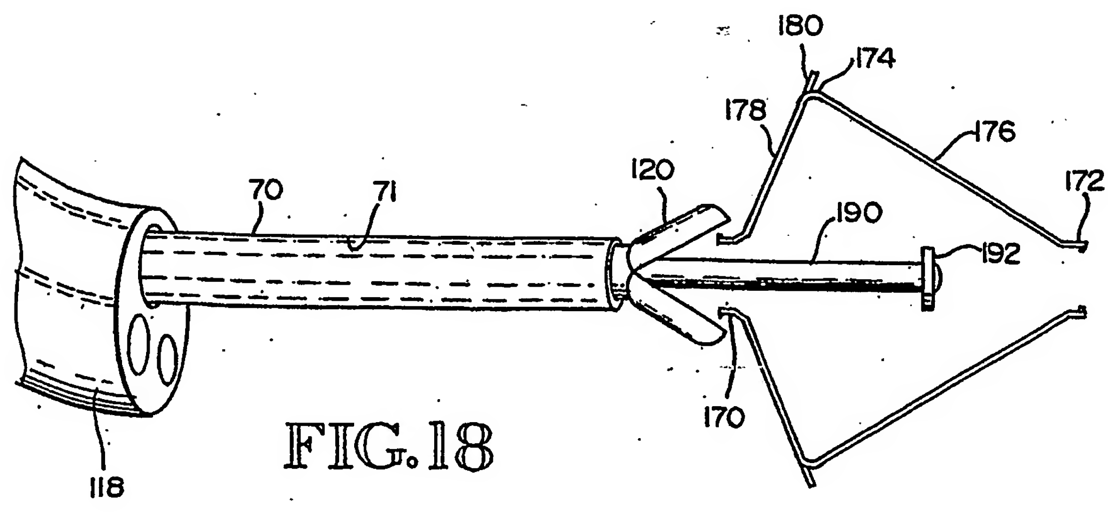


FIG. 18

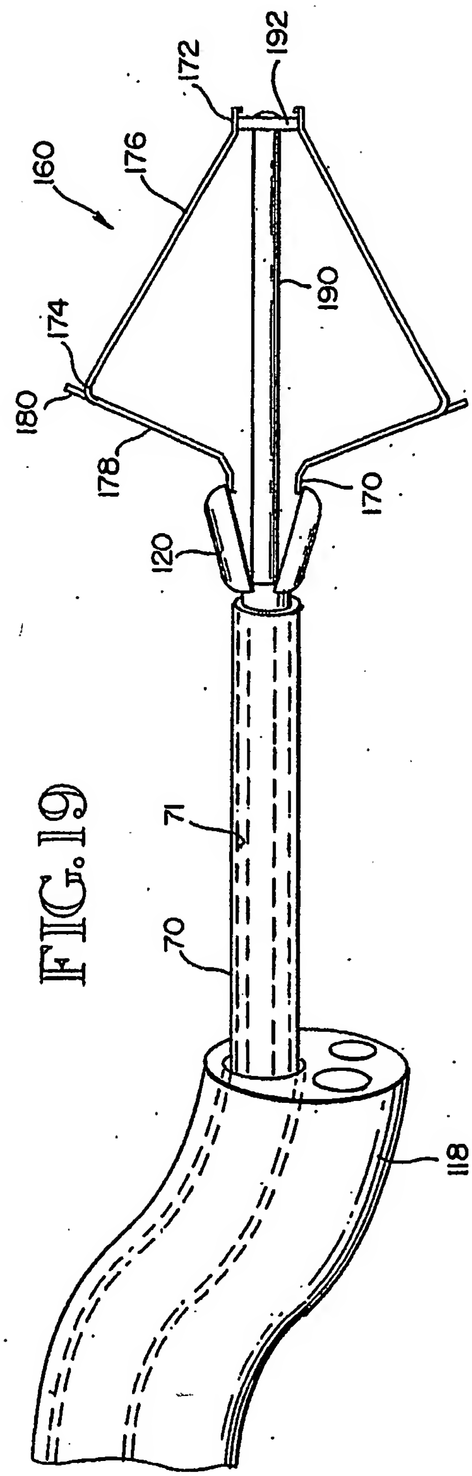

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FIG. 19

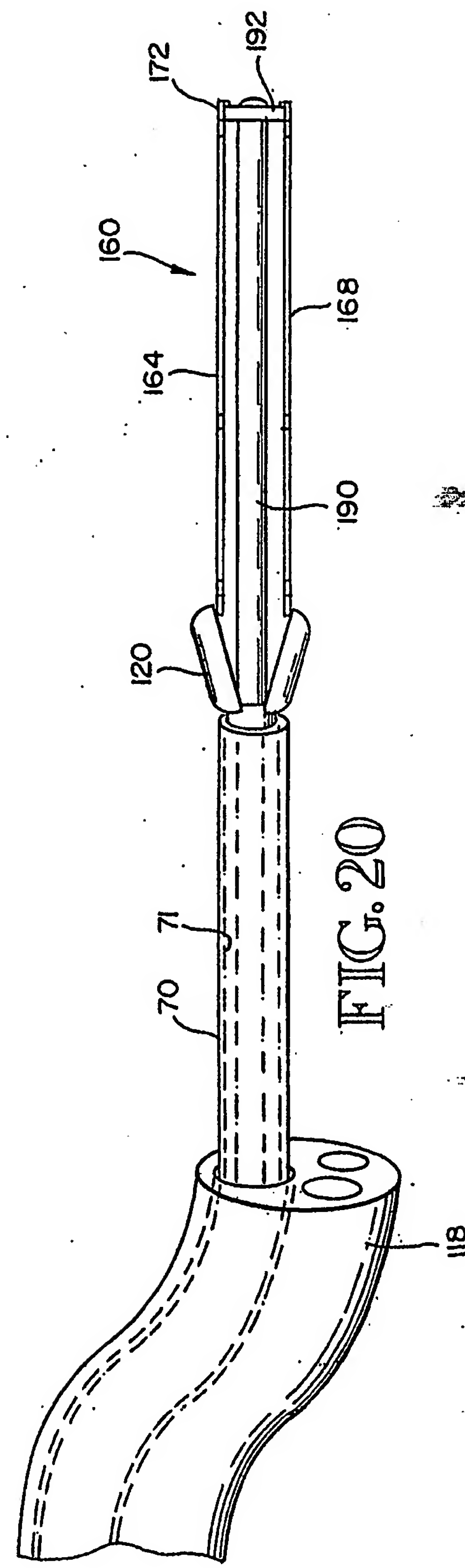
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FIG. 20